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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,400	06/27/2003	Michael J. Pugia	MSA-3453	7945

7590

12/29/2004

Elizabeth A. Levy
Bayer HealthCare LLC
63 North Street
Medfield, MA 02052

EXAMINER

SINES, BRIAN J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/608,400

Applicant(s)

PUGIA ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE f this communication appears on th cover sheet with the correspondence address --
Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/21/2004 (examiner interview summary).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 17-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Pri rity under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I comprising claims 1 – 16 in the reply filed on 12/21/2004 (examiner interview summary record) is acknowledged.

Claims 17 – 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

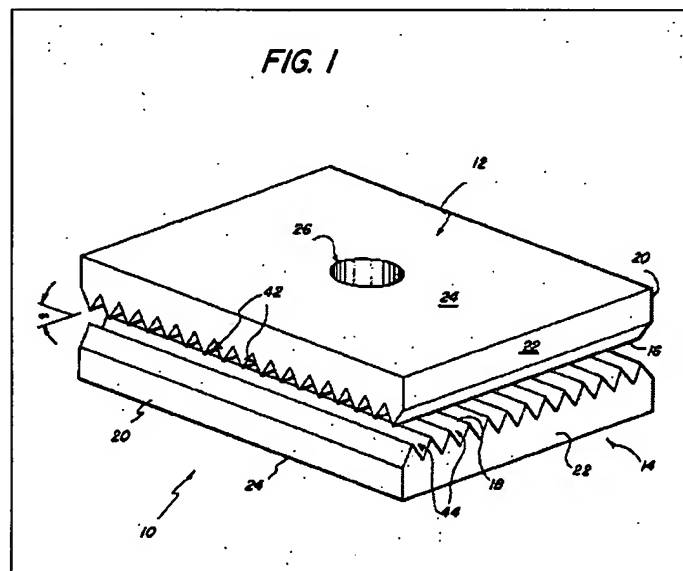
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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1. Claims 1, 5 – 9 and 13 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus (U.S. Pat. No. 4,233,029) in view of Przybylowicz et al. (U.S. Pat. No. 3,992,158).

Regarding claims 1 and 8, Columbus teaches an analytical apparatus (10) comprising: at least one space (e.g., the space between interior surfaces 16 & 18) for containing a test sample and a reagent on a substrate (e.g., the bottom surface 18); a microstructure (grooves 42 & 44) disposed in the space for directing the test sample over the substrate in a uniform manner. As fluid is introduced into the space via port 26, the introduced fluid would displace and thereby purge any air contained within this space during use (see col. 3, line 16 – col. 4, line 68; figure 1).



Columbus is silent to specifically teaching that a reagent or conditioning reagent is immobilized on a substrate surface. Although Columbus does teach that it can be desirable to include a reagent disposed on at least a portion of one or both substrate surfaces as disclosed by Przybylowicz et al. (see col. 9, lines 50 – 68). Przybylowicz et al. do teach the immobilization of reagents on a substrate layer contained within an

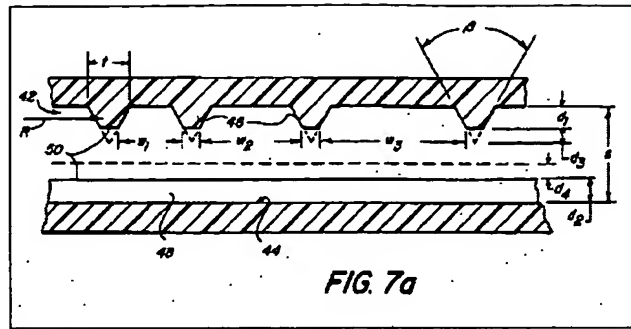
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analytical microfluidic apparatus (see col. 8, lines 44 – 66). Hence, as evidenced by Przybylowicz et al., a person of ordinary skill in the art would have recognized the suitability of incorporating the use of immobilized reagents within an analytical apparatus for the intended purpose of facilitating effective sample analysis (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of immobilized reagents, as taught by Przybylowicz et al., with the analytical apparatus disclosed by Columbus. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate immobilized reagents onto the substrate surface of the Columbus apparatus in order to facilitate effective sample analysis.

Regarding claim 5, Columbus teaches that the microstructure (e.g., groove 42) is also positioned above the substrate (e.g., substrate surface 18) (see figure 1).

Regarding claim 6, Columbus teaches that the microstructure (e.g., groove 44) can also be in contact and further integrated within the substrate (e.g., substrate surface 18) (see figure 1).

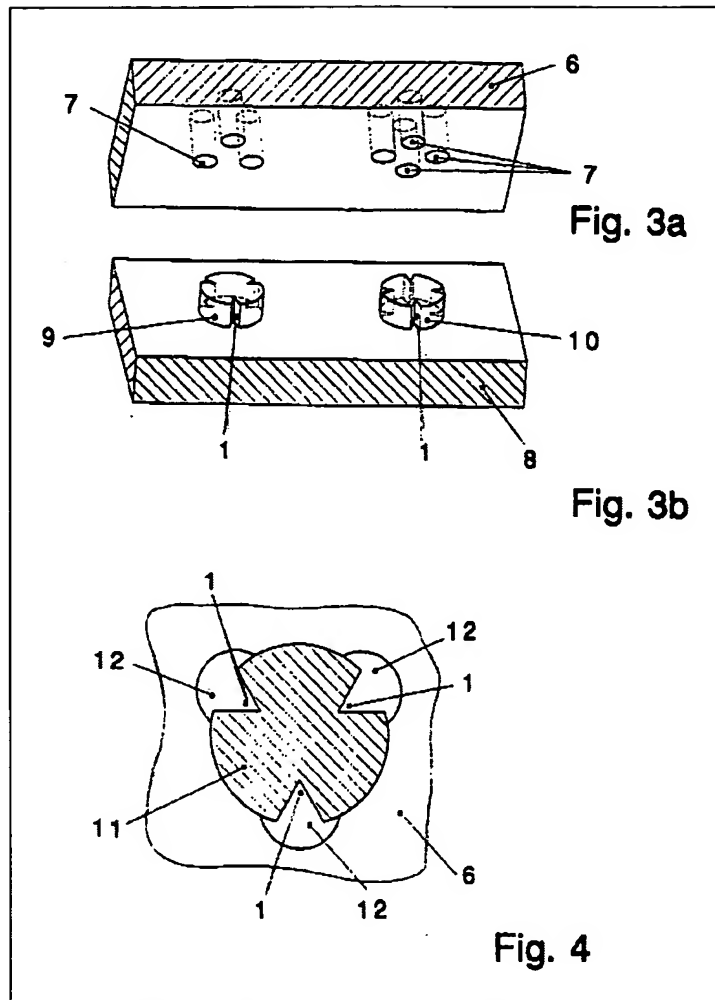
Regarding claim 7, Columbus also teaches the incorporation of a microstructure (truncated ridges 46) comprising a ramp or slanted portion and a substrate plateau (e.g., the flat top surface of the truncated ridge 46) (see col. 8, lines 1 – 67; figure 7a).

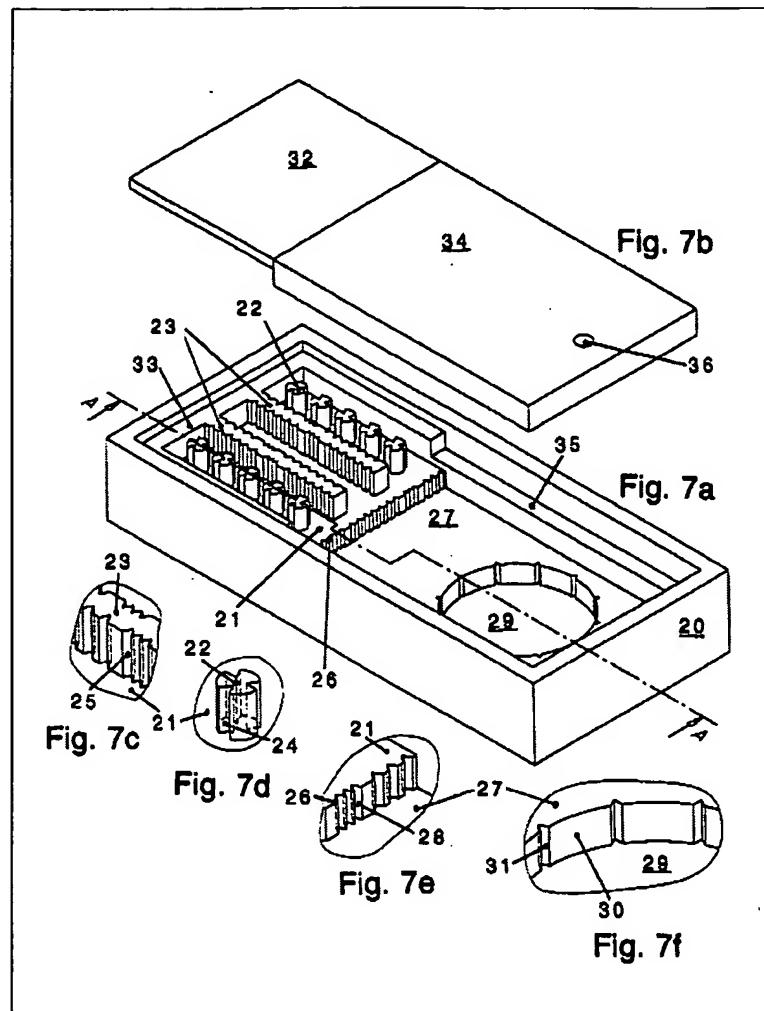


Regarding claims 9 and 13 – 16, as discussed above, Columbus teaches all of the apparatus structure recited in the claimed method, which merely recites the conventional operation of that apparatus structure. Regarding claim 9, the recited well structure is essentially equivalent to the space (e.g., the space between interior surfaces 16 & 18) for containing a test sample and a reagent on a substrate (e.g., the bottom surface 18) contained within the apparatus of Columbus, as discussed above. Therefore, it would have been obvious to a person of ordinary skill in the art to perform the methodology recited in the instant claims upon the apparatus of Columbus, as such is the intended operation of that apparatus.

2. Claims 2 – 4 and 10 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus in view of Przybylowicz et al., as applied to claims 1, 5 – 9 and 13 – 16 above, and further in view of Peters (U.S. Pat. No. 6,296,126 B1).

Regarding claim 2, Neither Columbus nor Przybylowicz et al. teach the incorporation of microstructures comprising post or column structures disposed at a right angle to the flow of the test sample. Peters does teach the use of post or column structures (9, 10 & 22) within an analytical microfluidic apparatus for facilitating effective fluid flow within the apparatus (see col. 3, line 30 – col. 39; figures 3b & 7a).





Hence, as evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of these post or column structures within an analytical microfluidic apparatus for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these post structures within a microfluidic apparatus for facilitating effective fluid control. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)

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(see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of an array of post structures comprising one or more than one column of posts disposed at a right angle to the flow of fluid within the microfluidic apparatus of Columbus.

Regarding claim 3, as illustrated in figure 7a, Peters indicate that multiple columns of posts (22 & 23) may be incorporated into the apparatus. In addition, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a second column of posts, as indicated by Peters, within the Columbus apparatus in order to facilitate effective fluid flow control.

Regarding claim 4, Peters does teach the incorporation of wedge-shaped cut-out structures (columnar projection 9 having wedge-shaped cut-outs 1) within a microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4). Consequently, a person of ordinary skill in the art would have recognized the suitability of incorporating such wedge-shaped cut-out post structures within an analytical microfluidic device for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate post structures comprising at least one wedge-shaped cut-out as recited in claim 4, to provide for effective fluid flow control.

Regarding claims 10 – 12, as discussed above, Columbus in view of Przybylowicz et al. and Peters teaches all of the apparatus structure recited in the

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claimed method, which merely recites the conventional operation of that apparatus structure. Therefore, it would have been obvious to a person of ordinary skill in the art to perform the methodology recited in the instant claims upon the apparatus taught by Columbus in view of Przybylowicz et al. and Peters, as such is the intended operation of that apparatus.

Conclusion

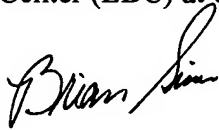
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Columbus teaches an additional analytical microfluidic apparatus utilizing capillary transport. Bowen teaches a diagnostic apparatus utilizing a fluid transport surface comprising projections to assure the uniform spreading of test fluid within the apparatus during operation, and including immobilized reagents. Buechler teaches an assay device utilizing immobilized reagents for sample analysis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Brian Kim", is located below the main text block.